IN THE

United States Court of Appeals for the Ninth Circuit

No. 13-17017

NICOLE WEBER,

Plaintiff-Appellant,

v.

ALLERGAN, INC.,

Defendant-Appellee.

On Appeal from an Order Dated September 25, 2013
Issued by United States District Court for the District of Arizona
(Honorable Susan R. Bolton)
At 2:12-cv-02388-SRB

BRIEF OF PLAINTIFF-APPELLANT NICOLE WEBER

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JURISDICTIONAL STATEMENT

The United States District Court for the District of Arizona ("District Court") had subject matter jurisdiction over this matter pursuant to 28 U.S.C. § 1332(a)(1), as "the matter in controversy exceeds the sum or value of $75,000, exclusive of interest and costs, and is between … citizens of different States." The United States Court of Appeals for the Ninth Circuit has subject matter jurisdiction over this appeal pursuant to 28 U.S.C. § 1291, which provides in pertinent part as follows: "The courts of appeals … shall have jurisdiction of appeals from all final decisions of the district courts of the United States."

On September 25, 2013, the District Court entered an Order ("September 25 Order") granting the Rule 12(b)(6) motion to dismiss ("Motion to Dismiss") filed on behalf of Defendant-Appellee Allergan, Inc. ("Allergan").[1] The September 25 Order constitutes a final order because it disposed of all claims as to all parties. On October 7, 2013, Plaintiff-Appellant Nicole Weber filed a Notice of Appeal of the September 25 Order.[2] The Notice of Appeal is timely pursuant to Federal Rule of Appellate Procedure 4(a)(1), as it was "filed with the district clerk within 30 days after entry of the judgment or order appealed from."

[1] See September 25 Order, Excerpts of Record 001-007.
[2] See Notice of Appeal, Excerpts of Record 194-195.

STATEMENT OF THE ISSUES PRESENTED FOR REVIEW

The principal issue on appeal is whether the District Court committed legal error when it held that Ms. Weber, in her Second Amended Complaint, failed to adequately plead claims against Defendant-Appellee Allergan, Inc. ("Allergan") for strict products liability (manufacturing defect) and negligence.

Pursuant to Circuit Rule 28-2.5, and such other rules as are applicable, we note the following information. The issue of whether the Second Amended Complaint adequately pleads claims for strict products liability (manufacturing defect) and negligence was raised in Allergan's Motion to Dismiss,[3] Ms. Weber's opposition thereto,[4] and Allergan's reply to Ms. Weber's opposition. The District Court ruled on the matter on September 25, 2013, when it issued its Order granting the Motion to Dismiss.[5] The applicable standard of review of the District Court's Order is *de novo*.[6]

[3] See Motion to Dismiss, Excerpts of Record 167-176.

[4] See "Plaintiff Nicole Weber's Memorandum of Law in Opposition to Allergan, Inc.'s Motion to Dismiss," Excerpts of Record 177-193.

[5] See September 25 Order, Excerpts of Record 001-007.

[6] See, e.g., Decker v. Advantage Fund Ltd., 362 F.3d 593, 595-96 (9th Cir. 2004) ("A district court's decision to grant a motion to dismiss pursuant to Rule 12(b)(6) is reviewed *de novo*.") (citation omitted).

STATEMENT OF THE CASE

I.

The following allegations are set forth in Ms. Weber's Second Amended Complaint. Under well-established precedent, on appeal, this Court "accept[s] the plaintiffs' allegations as true and construe[s] them in the light most favorable to the plaintiffs."[7]

Allergan is the designer, manufacturer, and distributor of Natrelle silicone gel-filled breast implants.[8] Breast implants in general, and silicone gel-filled implants in particular, have been the subject of much scrutiny.[9] In 1992, the Food and Drug Administration ("FDA") placed a moratorium on the sale of silicone gel-filled implants.[10] Subsequently, manufacturers including Allergan initiated clinical trials to study the safety and efficacy of silicone gel-filled implants.[11] In November 2006, the FDA approved of silicone gel-filled breast implants returning to the market.[12] As a condition of approval, however, the FDA required Allergan to conduct post-approval studies monitoring the performance and safety of the implants.[13]

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[7] See Siracusano v. Matrixx Initiatives, Inc., 585 F.3d 1167 (9th Cir. 2009) (citation omitted).

[8] See Second Amended Complaint, Excerpts of Record 070, ¶ 6.

[9] See Second Amended Complaint, Excerpts of Record 070, ¶ 7.

[10] See Second Amended Complaint, Excerpts of Record 071, ¶ 10.

[11] See Second Amended Complaint, Excerpts of Record 071, ¶ 11.

[12] See Second Amended Complaint, Excerpts of Record 071, ¶ 12.

[13] See Second Amended Complaint, Excerpts of Record 071, ¶ 13.

Specifically, the FDA required Allergan to conduct a large-scale ten-year study collecting data related to safety and effectiveness.[14] In order to comply with the FDA's directive and continue to benefit from the ability to sell silicone implants, Allergan set out to enroll 50,000 patients in a nationwide study called the Breast Implant Follow-Up Studies program ("BIFS").[15] Upon information and belief, Bryan W. Gawley, M.D., a plastic surgeon based in Scottsdale, Arizona, was selected by Allergan to serve as an investigator for BIFS.[16] At all times, Dr. Gawley was acting as Allergan's agent.[17]

II.

In March 2009, at the age of fifty-three, Ms. Weber was diagnosed with zero-staged breast cancer.[18] Ms. Weber's cancer surgeon recommended four surgeons specializing in reconstructive surgery, one of whom was Dr. Gawley.[19]

On July 8, 2009, Ms. Weber had an appointment with Dr. Gawley to discuss reconstructive surgery following her bilateral mastectomy.[20] Dr. Gawley repeatedly represented to Ms. Weber that silicone implants were very safe,[21] as follows:

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[14] See Second Amended Complaint, Excerpts of Record 071, ¶ 14.
[15] See Second Amended Complaint, Excerpts of Record 071, ¶¶ 15-18.
[16] See Second Amended Complaint, Excerpts of Record 071, ¶¶ 17, 31.
[17] See Second Amended Complaint, Excerpts of Record 071, ¶ 17.
[18] See Second Amended Complaint, Excerpts of Record 071, ¶ 19.
[19] See Second Amended Complaint, Excerpts of Record 071, ¶ 20.
[20] See Second Amended Complaint, Excerpts of Record 072, ¶ 21.
[21] See Second Amended Complaint, Excerpts of Record 072, ¶ 22.

- Dr. Gawley advised Ms. Weber that the problems previously associated with silicone implants had been remedied before the implants were brought back on the market in 2006.[22]
- Dr. Gawley further stated that there was a fringe group of women who claimed they experienced problems attributable to silicone implants, but those women were just "kooks."[23]
- Dr. Gawley represented that there was absolutely no chance of rupture, and that he had no problems with the new silicone implants in his practice.[24]
- When Ms. Weber expressed concerns about the safety of silicone implants, Dr. Gawley related a well-rehearsed story of his one and only problem case, which involved a woman who was a pole dancer who repeatedly banged her breast on the pole, causing her implant to explode. Dr. Gawley implied to Ms. Weber that, unless she was planning on pole dancing, there was no chance of rupture.[25]

Dr. Gawley never discussed the risks associated with a bleed and never disclosed that silicone could bleed into patients' bodies.[26] Dr. Gawley further

[22] See Second Amended Complaint, Excerpts of Record 072, ¶ 23.
[23] See Second Amended Complaint, Excerpts of Record 072, ¶ 26.
[24] See Second Amended Complaint, Excerpts of Record 072, ¶ 27.
[25] See Second Amended Complaint, Excerpts of Record 072, ¶ 28.
[26] See Second Amended Complaint, Excerpts of Record 072, ¶ 29.

stated that silicone implants were natural looking, and that Ms. Weber would not be happy with the outcome if she chose saline implants.[27] Clearly, Dr. Gawley's goal was to convince Ms. Weber to choose silicone implants over saline.[28] On information and belief, Dr. Gawley's statements and representations to Ms. Weber were all based on information and marketing materials that Allergan provided to him.[29]

III.

On July 28, 2009, Ms. Weber underwent a radical mastectomy at Piper Surgery Center in Scottsdale, Arizona.[30] Immediately following this procedure, Dr. Gawley placed Alloderm tissue expanders in order to prepare for implant surgery in several months.[31] On or about December 2, 2009, during a pre-operative appointment, Dr. Gawley's staff asked Ms. Weber to fill out a questionnaire that they said would help cancer patients; Ms. Weber was not told that the questionnaire was actually part of the FDA-ordered study to determine whether the implants were safe.[32] The name of the contractor administering the survey was only identified as BIFS and its relation to Allergan was not identified.[33]

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[27] See Second Amended Complaint, Excerpts of Record 072, ¶ 24.
[28] See Second Amended Complaint, Excerpts of Record 072, ¶ 25.
[29] See Second Amended Complaint, Excerpts of Record 072, ¶ 30.
[30] See Second Amended Complaint, Excerpts of Record 073, ¶ 31.
[31] See Second Amended Complaint, Excerpts of Record 073, ¶ 32.
[32] See Second Amended Complaint, Excerpts of Record 073, ¶ 33.
[33] See Second Amended Complaint, Excerpts of Record 073, ¶ 34.

Ms. Weber agreed to fill out the questionnaire in order to help other cancer patients.[34] On December 2, 2009, Ms. Weber registered with BIFS and was assigned a participant registration code.[35]

On December 21, 2009, Ms. Weber underwent surgery to substitute the tissue expanders for the Natrelle implants.[36] Prior to this surgery, other than the zero-staged breast cancer, Ms. Weber was a healthy individual and lived a healthy lifestyle.[37] Ms. Weber enjoyed exercise and outdoor activities; in fact, she organized and played in an employer-sponsored soccer league in 2007 and 2008.[38]

On August 10, 2010, Ms. Weber had a follow-up appointment with Dr. Gawley, at which she presented with complaints of severe pressure and discomfort from tightening of the implants.[39] When Ms. Weber expressed concern about how tight and uncomfortable the implants felt, Dr. Gawley responded by saying that she was only experiencing tightness and discomfort because she was swimming three times a week, and suggested that she stop doing the breaststroke.[40] Dr. Gawley said that there were no issues with the implants, and told Ms. Weber that she should simply face the reality that the implants were going to be tight.[41]

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[34] See Second Amended Complaint, Excerpts of Record 073, ¶ 35.
[35] See Second Amended Complaint, Excerpts of Record 073, ¶ 36.
[36] See Second Amended Complaint, Excerpts of Record 073, ¶ 37.
[37] See Second Amended Complaint, Excerpts of Record 073, ¶ 38.
[38] See Second Amended Complaint, Excerpts of Record 073, ¶ 39.
[39] See Second Amended Complaint, Excerpts of Record 073, ¶ 40.
[40] See Second Amended Complaint, Excerpts of Record 074, ¶¶ 41-42.
[41] See Second Amended Complaint, Excerpts of Record 074, ¶ 43.

Around August 21, 2010, Ms. Weber received the first annual survey from BIFS, and checked "no" next to every symptom on the list; breast tightening, however, was conspicuously absent from the list.[42]

From December 2010 to October 2011, Ms. Weber experienced symptoms that included (1) vision loss; (2) six weeks of daily migraines; (3) severe lung and breathing difficulties; (4) severe anxiety; (5) tinnitus; (6) severe vertigo; (7) a racing heartbeat; (8) large red strawberries on her arms, and fungal feet; (9) allergic reactions to all medications; and (10) severe chest spasms and tremors.[43] Ms. Weber's migraines were so severe that she required weekly visits to the emergency room, as well as an urgent care facility.[44] Ms. Weber also required an emergency room visit in connection with her lung and breathing problems.[45]

In March 2011, Ms. Weber's vision loss became significant.[46] Over the next year, in effort to discover a diagnosis, Ms. Weber sought evaluation and treatment from numerous ophthalmologists and neurologists.[47]

At the end of September 2011, Ms. Weber received the second follow-up survey from BIFS. This time, Ms. Weber checked "yes" next to numerous symptoms, including a change in the shape or size of the breast; anxiety; changes

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[42] See Second Amended Complaint, Excerpts of Record 074, ¶ 44.
[43] See Second Amended Complaint, Excerpts of Record 074, ¶ 45.
[44] See Second Amended Complaint, Excerpts of Record 074, ¶ 46.
[45] See Second Amended Complaint, Excerpts of Record 074, ¶ 47.
[46] See Second Amended Complaint, Excerpts of Record 074, ¶ 48.
[47] See Second Amended Complaint, Excerpts of Record 074, ¶ 48.

in mood or personality; chest pain; decreased visual acuity or double vision; depression; dizziness; eye inflammation; headaches; hearing and balance disturbances; insomnia; irritable bowel syndrome; ringing in the ears; strange movements in all or part of the body; and sun or light sensitivity.[48]

The survey form cautioned that she should contact her plastic surgeon if more than three items were checked.[49] On October 5, 2011, Ms. Weber had an appointment with Dr. Gawley, who advised that other professionals believed that the problems she was experiencing could be caused by the implants, and that they needed to be removed.[50] Ms. Weber asked Dr. Gawley if she had a rupture; he replied that her implants had not ruptured.[51] He further stated that the implants did not have to rupture to cause problems, and they could bleed into a patient's system even in the absence of a rupture.[52] Ms. Weber inquired about the severe neurological jerking that she was experiencing, and Dr. Gawley recommended that she see a neurologist; at that point, Ms. Weber mentioned that she knew a neurologist, Shafeq Lada, and he stated that he knew Dr. Lada well.[53] Notably, the note from the October 5, 2011, visit appears to be missing from her file.[54]

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[48] See Second Amended Complaint, Excerpts of Record 074-075, ¶ 49.
[49] See Second Amended Complaint, Excerpts of Record 075, ¶ 50.
[50] See Second Amended Complaint, Excerpts of Record 075, ¶ 51.
[51] See Second Amended Complaint, Excerpts of Record 075, ¶ 52.
[52] See Second Amended Complaint, Excerpts of Record 075, ¶ 53.
[53] See Second Amended Complaint, Excerpts of Record 075, ¶ 54.
[54] See Second Amended Complaint, Excerpts of Record 074, ¶ 56.

Ms. Weber told Dr. Gawley that she wanted to get tested for silicone sensitivity, and he wrote her a prescription for silicone testing.[55] When Ms. Weber took the prescription to the lab to get tested for silicone, the lab refused to fulfill it, as it had been written for "silicon" as opposed to "silicone."[56] As a result, Ms. Weber searched for an independent testing site.[57]

On October 12, 2011, Ms. Weber underwent testing at Arizona Center for Advanced Medicine, which demonstrated a severe generalized reaction to silicone.[58] Ms. Weber was advised that, in light of the test results, it was medically necessary for her to have the implants removed immediately.[59]

On October 14, 2011, Ms. Weber had a second visit with Dr. Gawley, the record of which is also missing from the medical records.[60] During the visit, Dr. Gawley said he spoke with Dr. Lada, and Dr. Lada said that the neurological issues could be related to the implants.[61] Ms. Weber scheduled explanation surgery with Dr. Gawley for October 18, 2011.[62]

The day before the surgery, Dr. Gawley advised Ms. Weber that he did not believe that her health problems had to do with the implants, but he would be

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[55] See Second Amended Complaint, Excerpts of Record 075, ¶ 57.
[56] See Second Amended Complaint, Excerpts of Record 075, ¶ 58.
[57] See Second Amended Complaint, Excerpts of Record 075, ¶ 59.
[58] See Second Amended Complaint, Excerpts of Record 075, ¶ 60.
[59] See Second Amended Complaint, Excerpts of Record 076, ¶ 61.
[60] See Second Amended Complaint, Excerpts of Record 076, ¶ 62.
[61] See Second Amended Complaint, Excerpts of Record 076, ¶ 63.
[62] See Second Amended Complaint, Excerpts of Record 076, ¶ 64.

happy to proceed with the explantation surgery the following day as planned.[63] Given that conversation, Ms. Weber did not feel comfortable proceeding with the surgery with Dr. Gawley.[64] In light of her unease, Ms. Weber cancelled the surgery with Dr. Gawley and rescheduled with Lu-Jean Feng, M.D., who had advised that her health problems were caused by the implants.[65]

On October 20, 2011, Ms. Weber underwent explantation surgery with Dr. Feng, who attributed all of Ms. Weber's health issues, including her vision problems, to Allergan's implants.[66] The pathology report documented associated foreign body-type multinucleated giant cells surrounding the implants.[67]

After the implants were removed, Ms. Weber gradually began to regain her health with respect to her tinnitus, chest spasms, migraines, foot funguses, and anxiety.[68] As the result of the bleed, however, Ms. Weber's body continues to contain neurotoxic levels of manganese, and Ms. Weber continues to experience significant vision issues, extreme chemical sensitivity to all medications, and immune system problems.[69] Perhaps most significantly, in May 2012, Ms. Weber was diagnosed with autoimmune retinopathy, an eye condition associated with autoantibodies that are generated to attack foreign bodies/offending agents and

[63] See Second Amended Complaint, Excerpts of Record 076, ¶ 65.
[64] See Second Amended Complaint, Excerpts of Record 076, ¶ 66.
[65] See Second Amended Complaint, Excerpts of Record 076, ¶ 67.
[66] See Second Amended Complaint, Excerpts of Record 076, ¶ 68.
[67] See Second Amended Complaint, Excerpts of Record 076, ¶ 69.
[68] See Second Amended Complaint, Excerpts of Record 076, ¶ 70.
[69] See Second Amended Complaint, Excerpts of Record 076, ¶ 71.

begin to attack the retina.[70] The condition involves color distortion, light problems, increasing dimness, and ultimately blindness.[71] Ms. Weber was also examined by Dr. Stephen Foster of Harvard Medical School; Dr. Foster explained that her prognosis was poor, and she had almost no hope of being cured.[72]

IV.

Allergan's "Directions for Use" state that "[s]mall quantities of low molecular weight (LMW) silicone compounds, as well as platinum (in zero oxidation state), have been found to diffuse (bleed) through an intact implant shell."[73] A few sentences later, Allergan states as follows: "Allergan performed a laboratory test to analyze the silicones and platinum (used in the manufacturing process), which may bleed out of intact implants into the body. Over 99% of the LMW silicones and platinum stayed in the implant. The overall body of available evidence supports that the extremely low level of gel bleed is of no clinical consequence."[74] Allergan's product literature separately states that any data showing that breast implants lead to vision loss or any neurological issue is "insufficient or flawed."

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[70] See Second Amended Complaint, Excerpts of Record 077, ¶¶ 72, 73.

[71] See Second Amended Complaint, Excerpts of Record 077, ¶ 73.

[72] See Second Amended Complaint, Excerpts of Record 077, ¶ 75.

[73] See Second Amended Complaint, Excerpts of Record 077, ¶ 77; see also Exhibit A to Second Amended Complaint, Excerpts of Record 094 (underlining added, boldface deleted).

[74] See Second Amended Complaint, Excerpts of Record 077, ¶ 77; see also Exhibit A to Second Amended Complaint, Excerpts of Record 094 (underlining added).

Thus, (1) the breast implants when properly manufactured may occasionally bleed in the absence of rupture, but the bleed is an "extremely low level of gel bleed" that is "of no clinical consequence"; and (2) the implants when properly manufactured do not cause vision loss or neurological issues.[75] The nature and extent of Ms. Weber's injuries, including her significant vision loss and neurological issues, evidence a significant gel bleed, as opposed to an "extremely low level of gel bleed" that is "of no clinical consequence."[76] Indeed, by the very definition of "no clinical consequence," if Ms. Weber suffered a serious adverse reaction to the silicone that bled through the implants that was of clinical consequence, far more than an "extremely low level" of silicone gel bled through the implants.[77] The occurrence of a significant gel bleed, the presence of neurotoxic levels of manganese, and the permanent vision loss in Ms. Weber's case evidences that (1) the implants Ms. Weber received were different from those approved by the FDA; (2) the implants deviated from the FDA-approved product specifications; and (3) the manufacturing of the implants that Ms. Weber received deviated from federal requirements.[78]

Moreover, in a publicly available FDA report on Allergan's breast implants ("FDA Report" or "Report"), the FDA advised that, since Allergan began post-

[75] See Exhibit A to Second Amended Complaint, Excerpts of Record 101.
[76] See Second Amended Complaint, Excerpts of Record 077, ¶ 77.
[77] See Second Amended Complaint, Excerpts of Record 078, ¶ 81.
[78] See Second Amended Complaint, Excerpts of Record 078, ¶ 82.

approval studies on June 30, 2009, Allergan evaluated 2,665 devices in the laboratory, and found 900 to be defective due to openings in the shell.[79] On pages 17-18 of the Report, the FDA stated that, of these 900 defective devices, twenty-six suffered from "manufacturing defects," and of these 900 defective devices, an additional 336 had defects whose origins Allergan failed to identify.[80] At the motion-to-dismiss stage, Ms. Weber was entitled to the inference that a proportionate share of these additional 336 devices suffered from manufacturing defects.[81]

Moreover, the FDA separately stated that "5.9 percent" of the implants "had 'Gel Related Observations,' with defects related to gel-related characteristics without loss of shell integrity."[82] Ms. Weber expressly alleged in her Second Amended Complaint that, without discovery, it is unclear whether the FDA and Allergan were referring to manufacturing defects, or design defects.[83]

V.

Count I of the Second Amended Complaint, styled "Strict Products Liability (Manufacturing Defect)," contains the following allegations against Allergan:

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[79] See Second Amended Complaint, Excerpts of Record 079, ¶ 83; see also Exhibit B to Second Amended Complaint, Excerpts of Record 121.

[80] See Second Amended Complaint, Excerpts of Record 079, ¶ 84; see also Exhibit B to Second Amended Complaint, Excerpts of Record 121.

[81] See Second Amended Complaint, Excerpts of Record 079, ¶ 84.

[82] See Second Amended Complaint, Excerpts of Record 079, ¶ 85; see also Exhibit B to Second Amended Complaint, Excerpts of Record 121.

[83] See Second Amended Complaint, Excerpts of Record 079, ¶ 85.

86. Plaintiff incorporates by reference all other paragraphs of this complaint as if fully set forth herein.

87. At all times relevant hereto, Allergan was in the business of developing, testing, marketing, promoting and utilizing the subject implants.

88. Allergan tested, marketed, promoted and/or sold the implants utilized during plaintiff's surgery and Dr. Gawley sold the implants to plaintiff.

89. Upon information and belief, the implants utilized in surgery were expected to, and did in fact, reach the facility in the condition in which they left the manufacturing facility of Allergan.

90. Allergan manufactured and sold a product that was unreasonably dangerous at the time it left Allergan's control, due to the presence of a manufacturing defect.

91. The implants contained a manufacturing defect which Allergan did not intend and the FDA did not allow and, as a result, they failed to perform as safely as an ordinary consumer would expect when the product is used in a reasonably foreseeable manner.

92. The significant bleeding of silicone that occurred here, and neurotoxic levels of manganese in Ms. Weber's system, are inconsistent with specifications of the product as submitted to the FDA for approval, and evidence of a manufacturing defect.

93. Allergan's actions, as set forth above, violate the FDA's Quality System Regulations and Current Good Manufacturing Practices, 21 C.F.R. § 820.1, et seq., which among other things "require each manufacturer to put in place processes to test products for compliance with product specifications, to check and document compliance with product specifications before products are accepted for sale and use, and to identify and control nonconforming products." See, e.g.,

Bausch v. Stryker Corp., 630 F.3d 546 (7th Cir. 2010) (citing 21 C.F.R. §§ 820.72-820.90).

94. "The failure to comply with any applicable provision in this part [of the regulations] renders a device adulterated under section 501(h) of the act. Such device, as well as any person responsible for the failure to comply, is subject to regulatory action." See id. (quoting 21 C.F.R. § 820.1(c)).

95. Allergan's actions also violate 21 U.S.C. § 360e(d)(2), which require[s] products to be safe and effective.

96. As a direct and proximate result of defendant's actions, as set forth above, plaintiff has in the past been and will in the future continue to be compelled to expend monies and incur obligations for medical care and treatment; plaintiff has also incurred and will hereafter continue to incur other financial expenses or losses … .

97. Plaintiff has sustained and makes claims for pain and suffering, loss of physical function, permanent physical, mental, dignitary and psychological injuries, loss of life's pleasures, loss of earning capacity, and any and all the damages to which she is or may be entitled under the law … .[84]

VI.

Ms. Weber's Second Amended Complaint was filed on May 8, 2013.[85] On May 21, 2013, Allergan filed its Motion to Dismiss.[86] Therein, Allergan argued

[84] See Second Amended Complaint, Excerpts of Record 079-081, ¶¶ 86-97. Count Two, for negligence, incorporates these allegations, and makes related allegations. See Second Amended Complaint, Excerpts of Record 081-082, ¶¶ 98-102.

[85] See generally Second Amended Complaint, Excerpts of Record 069-166. Prior in time, on November 28, 2012, Ms. Weber filed an Amended Complaint as of right pursuant to Federal Rule of Civil Procedure 15(a). See generally Amended Complaint, Excerpts of Record 009-023. Subsequently, Allergan filed a motion to

that Ms. Weber had failed to adequately plead a "parallel" claim, and her claims were therefore preempted by the Medical Device Amendments ("MDA") to the Food, Drug, and Cosmetic Act.[87] Ms. Weber filed a comprehensive opposition,[88] to which Allergan filed a reply.[89]

On September 25, 2013, the trial court issued a seven-page Order dismissing the Second Amended Complaint. In its Order, the trial court erroneously determined that Ms. Weber had failed to state an adequate "parallel" claim:

> Plaintiff alleges in the Second Amended Complain[t] that Defendant did not disclose the "significant gel bleed" that she experienced. (SAC ¶¶ 78-79.) Plaintiff alleges that a "significant gel bleed" was not a known risk of a properly manufactured Natrelle Style 20 implant and that the occurrence of a "significant gel bleed" and resulting presence of neurotoxic levels of manganese are proof that Defendant's manufacture of the implants deviated from federal requirements. (*Id.* ¶¶ 80, 82, 92.)
>
> However, Plaintiff has not alleged facts showing that a significant gel bleed occurred. Plaintiff alleges that the results of her October 2011 pathology report showing "multinucleated giant cells surrounding the implants" and "the nature and extent" of her injuries evidence a significant gel bleed. (*Id.* ¶¶ 69, 77.) Plaintiff also alleges that her body contained documented neurotoxic levels of manganese as a result of the gel bleed. (*Id.* ¶ 76.) These allegations are conclusory because

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dismiss, and, following oral argument, the District Court dismissed Ms. Weber's First Amended Complaint without prejudice. See generally Excerpts of Record 024-068.

[86] See generally Motion to Dismiss, Excerpts of Record 167-176.

[87] See generally Motion to Dismiss, Excerpts of Record 167-176.

[88] See generally "Plaintiff Nicole Weber's Memorandum of Law in Opposition to Allergan, Inc.'s Motion to Dismiss," Excerpts of Record 177-193.

[89] Allergan's reply was filed at Docket No. 41.

they essentially assume that a significant gel bleed occurred based on the results of Plaintiff's pathology report, the nature and extent of her injuries, and the levels of manganese in her system. To state a plausible claim for relief, Plaintiff must allege facts showing that a significant gel bleed occurred. It is conclusory to allege that Plaintiff's serious health problems evidence a gel bleed greater than that contemplated by the FDA in its approval of the implants. [Footnote 1: This is especially so in light of Plaintiff's allegation that her test showed a severe generalized reaction to silicone. (SAC ¶ 60.)]

Plaintiff's allegations that the presence of neurotoxic levels of manganese and that the toxicology report showed foreign body-type multinucleated giant cells surrounding the implants evidence a manufacturing defect also are conclusory. (*Id.* ¶ 92.) These two factual allegations do not show how the implants were different from those approved by the FDA, how the manufacture of the implants deviated from federal requirements, or in what way the implants were inconsistent with and deviated from the product specifications submitted to the FDA, as Plaintiff alleges. (*Id.* ¶ 82.) Plaintiff's allegations are deficient because it cannot be assumed that these findings evidence a "significant gel bleed" and a manufacturing defect or deviation from federal requirements.

Plaintiff's allegation that Defendant has determined that a number of devices are defective due to "openings in the shell" or for unidentified reasons does not show a violation of federal regulations or requirements in this case. (*Id.* ¶¶ 83-84.) Plaintiff's reference to federal regulations that require a manufacturer to comply with "good manufacturing practices" does not show how Defendant deviated from federally-approved manufacturing requirements. (*Id.* ¶¶ 93-94.)

III. CONCLUSION

Plaintiff's allegations in the Second Amended Complaint are insufficient to state a parallel claim that defeats MDA

preemption. Plaintiff's Second Amended Complaint is dismissed.[90]

[90] See September 25 Order, Excerpts of Record 001-007.

SUMMARY OF THE LEGAL ARGUMENT

In Riegel v. Medtronic, Inc., the United States Supreme Court held that 21 U.S.C. § 360k preempts state-law tort suits that seek to impose requirements upon the manufacturer of a Class III medical device that received premarket approval, but only where those state-law requirements are different from, or in addition to, the FDA's requirements.[91] The Supreme Court noted that § 360k does not preempt "parallel" claims – that is to say, claims that "'parallel,' rather than add to, federal requirements."[92]

In this matter, the District Court correctly acknowledged the viability of parallel claims, but committed legal error in holding that the Second Amended Complaint does not plausibly allege parallel claims for products liability (manufacturing defect) and negligence. In doing so, the District Court essentially required Ms. Weber to prove her case at the pleading stage through direct evidence only and with absolute certainty, a standard far more stringent than the plausibility standard announced by the United States Supreme Court in Bell Atlantic Corp. v. Twombly and clarified by the Court in Ashcroft v. Iqbal.[93]

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[91] See Riegel v. Medtronic, Inc., 552 U.S. 312, 320-21, 326, 327-30 (2008); see also Stengel v. Medtronic, Inc., 704 F.3d 1224, 1228 (9th Cir. 2013) (*en banc*) ("The rule that emerges from … cases [including Riegel] is that the MDA does not preempt a state-law claim for violating a state-law duty that parallels a federal-law duty under the MDA.").

[92] See id.

[93] See Bell Atlantic Corp. v. Twombly, 550 U.S. 544, 555 (2007); see also Ashcroft v. Iqbal, 556 U.S. 662, 679 (2009).

Allergan's directions and other product materials make clear that the "extremely low level of gel bleed" that is expected to occur on occasion "is of no clinical consequence." The nature and extent of the injuries sustained by Ms. Weber following implantation (including vision loss; multiple neurological issues; six weeks of daily migraines; severe lung and breathing difficulties; severe anxiety; tinnitus; severe vertigo; a racing heartbeat; large red strawberries on her arms, and fungal feet; allergic reactions to all medications; and severe chest spasms and tremors) were certainly of "clinical consequence." Similarly, Allergan's literature states that any data showing that breast implants lead to vision loss or any neurological issue is "insufficient or flawed," suggesting that the breast implants that Allergan designed, when properly manufactured, do not cause these issues. Ms. Weber has suffered severe and permanent vision loss, and experienced significant neurological issues, as the result of the implants. Ms. Weber was entitled to the reasonable inference that the implants she received were different from those approved by the FDA, and deviated from the FDA-approved product specifications and other federal requirements, including the "Quality System Regulations and Current Good Manufacturing Process requirements" that products be manufactured according to their design, and the device was therefore "adulterated under section 501(h) … [and] subject to regulatory action."[94]

[94] See Bausch v. Stryker Corp., 630 F.3d 546, 553-56 (7th Cir. 2010) (citing 21 C.F.R. § 820.1(c)), cert. denied, 132 S. Ct. 498 (2011).

It is beyond question that "[t]here are no special pleading requirements for product liability claims in general, or for Class III medical device claims in particular," and in such cases "[t]he federal standard of notice pleading applies, so long as the plaintiff alleges facts sufficient to meet the new 'plausibility' standard applied in Iqbal and Twombly."[95] This Ms. Weber has more than done. As such, the September 25 Order should be reversed, and this matter should be remanded to the District Court for discovery.

[95] See Bausch, 630 F.3d at 558.

LEGAL ARGUMENT

1. Introduction

21 U.S.C. § 360k(a), a provision of the MDA, prohibits a state from imposing upon a medical device manufacturer "any requirement– (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter." In Riegel v. Medtronic, Inc., the United States Supreme Court held that 21 U.S.C. § 360k preempts state-law tort suits that seek to impose requirements upon the manufacturer of a Class III medical device that are different from, or in addition to, the requirements imposed by the FDA.[96] The Supreme Court was careful to note that § 360k does not preempt "parallel" claims.[97]

Both Allergan and the District Court correctly recognized the viability of parallel claims alleging manufacturing defects, as this Court has.[98] The District Court, however, erroneously accepted Allergan's argument that Ms. Weber's Second Amended Complaint does not plausibly allege a manufacturing defect. The Second Amended Complaint sets forth a detailed and compelling claim that more than meets the pleading standards articulated in the case law.

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[96] See Riegel, 552 U.S. at 312, 320-21, 326, 327-30.
[97] See id.
[98] See Stengel, 704 F.3d at 1224.

2. As the Supreme Court Recognized in Riegel v. Medtronic, Inc., and this Court Recognized in Stengel v. Medtronic, Inc., the Medical Device Amendments Do Not Preempt "Parallel" Claims

21 U.S.C. § 360k(a), a provision of the MDA, prohibits a state from imposing upon a manufacturer "any requirement– (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter."

In Riegel v. Medtronic, Inc., the Supreme Court was called upon to decide whether § 360k preempted the plaintiff's design defect and breach of warranty claims involving a Class III device that had received premarket approval. The Supreme Court held that those particular claims were indeed preempted by § 360k because they would impose state-law requirements different from, or in addition to, federal ones imposed upon the device. The Court was careful to note that "[s]tate requirements are pre-empted under the MDA only to the extent that they are 'different from, or in addition to' the requirements imposed by federal law. … Thus, § 360k does not prevent a State from providing a damages remedy for claims premised on a violation of FDA regulations; the state duties in such a case 'parallel,' rather than add to, federal requirements."[99]

Since Riegel was decided, numerous courts presented with the issue have held that manufacturing defect claims parallel, rather than add to, federal

[99] See Riegel, 552 U.S. at 320-21, 326, 327-30.

requirements. In Hofts v. Howmedica Osteonics Corporation, the United States District Court for the Southern District of Indiana engaged in a lengthy analysis of Riegel and concluded that manufacturing defect claims are not preempted by the MDA.[100] The court observed, "it is clear that [the plaintiff] bases his tort claims on his allegations that [the manufacturer] failed to meet the FDA's requirements, not on allegations that [the manufacturer] failed to depart from or exceed those requirements," and a jury "could find that [the manufacturer] breached the duty of care it owed … by failing to adhere to … manufacturing requirements without imposing different or additional requirements."[101]

Similarly, in Warren v. Howmedica Osteonics Corporation, the United States District Court for the Eastern District of Missouri analyzed Riegel and concluded that the plaintiffs' manufacturing defect claims survived preemption.[102] Indeed, in Riegel, the Supreme Court itself noted that, after receiving premarket approval, "the MDA forbids the manufacturer to make, without FDA permission, changes in … manufacturing processes, labeling, or any other attribute … ."[103]

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[100] See Hofts v. Howmedica Osteonics Corporation, 597 F. Supp. 2d 830 (S.D.Ind. 2009).

[101] See id.

[102] See Warren v. Howmedica Osteonics Corporation, Docket No. 4:10 CV 1346, 2011 WL 1226975 at *4 (E.D.Mo. March 29, 2011); accord Burgos v. Satiety, Inc., Docket No. 10-CV-2680, 2011 WL 1327684 at *2 (E.D.N.Y. April 5, 2011) (same principle in the clinical trial context).

[103] See Riegel, 552 U.S. at 312.

In Bausch v. Stryker Corporation, the plaintiff brought "tort law claims based on manufacturing defects," and the manufacturer defendant moved to dismiss on the ground that such claims were preempted by Riegel. The Seventh Circuit readily concluded that manufacturing defect claims that parallel the FDA's requirements remain viable even after Riegel.[104] It observed, "Section 360k provides immunity for manufacturers of new Class III medical devices to the extent that they comply with federal law, but it does not protect them if they have violated federal law."[105]

The Seventh Circuit then held that manufacturers' violations of any FDA requirements, no matter how general those requirements are, constitute violations of federal law:

> [W]e do not see a sound legal basis for defendants' proposal to distinguish between general requirements and "concrete, device specific" requirements. Section 360k makes preemption a defense if a state seeks to impose on a manufacturer "any requirement—(1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter." 21 U.S.C. § 360k(a). We emphasize the phrase "any requirement." And federal law is clear:

[104] See Bausch, 630 F.3d at 552; see also Chambers v. Osteonics Corp., 109 F.3d 1243, 1248 (7th Cir. 1997) (holding that the MDA did not preempt a state-law manufacturing defect claim); Mitchell v. Collagen Corp., 126 F.3d 902, 913 n.6 (7th Cir. 1997) (observing that state-law negligence claims not preempted if they are based on claims that manufacturer did not adhere to FDA standards in the premarket approval process).

[105] See id. at 553.

> for manufacturers of Class III medical devices, the Quality System Regulations and Current Good Manufacturing Practices adopted by the FDA under its delegated regulatory authority are legally binding requirements "under this chapter." 21 C.F.R. § 820.1. "The failure to comply with any applicable provision in this part [of the regulations] renders a device adulterated under section 501(h) of the act. Such a device, as well as any person responsible for the failure to comply, is subject to regulatory action." 21 C.F.R. § 820.1(c).
>
> Defendants' proposed distinction between concrete, product specific requirements and more general requirements would also leave injured patients without any remedy for a wide range of harmful violations of federal law. The FDA regulations contain many requirements that are not concrete or product-specific, yet which are obviously vital to producing safe and effective medical devices. … We also assume that manufacturing processes are not perfect, despite what may be the best human efforts to achieve perfection. Perhaps more to the point, the FDA makes the same assumption, as is evident from its Quality System Regulations and Current Good Manufacturing Process requirements. The FDA regulations require each manufacturer to put in place processes to test products for compliance with product specifications, to check and document compliance with product specifications before products are accepted for sale and use, and to identify and control nonconforming products. 21 C.F.R. §§ 820.72 to 820.90.[106]

Stengel v. Medtronic, Inc., a unanimous decision issued by this Court, sitting *en banc*, recognized the viability of parallel claims. In Stengel, this Court framed "[t]he central question" as "whether the MDA preempts a state-law claim in which the state-law duty of care 'parallels' a federal-law duty imposed by the MDA," and

[106] See id. at 553-56.

"conclude[d] that such a state-law claim is not preempted … ." After analyzing cases in which the Supreme Court considered the preemptive force of the MDA, including Riegel, this Court concluded as follows: "The rule that emerges from these cases is that the MDA does not preempt a state-law claim for violating a state-law duty that parallels a federal-law duty under the MDA."[107]

Thus, Riegel does not preempt claims of a manufacturing defect, or claims that a device maker's actions violated FDA regulations (no matter how general).

3. The Pleading Standard that the District Court Applied to Ms. Weber's "Parallel" Claims Exceeded the Pleading Standard Under the Federal Rules of Civil Procedure

Under Federal Rule of Civil Procedure 8(a)(2), "[a] pleading that states a claim for relief must contain[] … a short and plain statement of the claim showing that the pleader is entitled to relief." In 1957, in Conley v. Gibson, the Supreme Court reiterated "the … rule that a complaint should not be dismissed for failure to state a claim unless it appears beyond doubt that the plaintiff can prove no set of facts in support of his claim which would entitle him to relief."[108] In May 2007, in Bell Atlantic Corp. v. Twombly, the Supreme Court abrogated the "no set of facts" standard in favor of a "plausibility" standard whereby "[f]actual allegations must be enough to raise a right to relief above the speculative level" to plausible.[109] The Court was careful to note that "[a]sking for plausible grounds does not impose a

[107] See Stengel, 704 F.3d at 1224.
[108] See Conley v. Gibson, 355 U.S. 41, 45-46 (1957).
[109] See Twombly, 550 U.S. at 555 (citation omitted).

probability requirement at the pleading stage; it simply calls for enough fact to raise a reasonable expectation that discovery will reveal evidence" supporting the plaintiff's claims.[110] In Ashcroft v. Iqbal, the Supreme Court clarified that "[w]hen there are well-pleaded factual allegations, a court should assume their veracity and then determine whether they plausibly give rise to an entitlement to relief."[111]

Indeed, following the Supreme Court's rulings in Twombly and Iqbal, federal courts continue to employ a "liberal motion to dismiss standard[] which requires taking Plaintiffs' allegations as true and drawing all reasonable inferences in their favor," so long as those allegations are plausible.[112] "It is not for the court to decide, at the pleading stage, which inferences are more plausible than other competing inferences, since those questions are properly left to the factfinder."[113]

Numerous circuits have held that this liberal pleading standard applies to products liability claims, even ones involving Class III medical devices. In Bausch, the Seventh Circuit readily held that "[t]here are no special pleading requirements for product liability claims in general, or for Class III medical device claims in particular" and further held that "[t]he federal standard of notice pleading applies, so long as the plaintiff alleges facts sufficient to meet the new

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[110] See id. (emphasis added).
[111] See Iqbal, 556 U.S. at 679.
[112] See, e.g., Bobbitt v. Milberg, LLP, 285 F.R.D. 424, 427 (D. Ariz. 2012).
[113] See Evergreen Partnering Group, Inc. v. Pactiv Corp., 720 F.3d 33, 45 (1st Cir. 2013) (citation omitted).

'plausibility' standard applied in Iqbal and Twombly."[114] The Seventh Circuit cautioned that District Courts "must keep in mind that much of the product-specific information about manufacturing needed to investigate such a claim fully is kept confidential by federal law" and "formal discovery is necessary before a plaintiff can fairly be expected to provide a detailed statement of the specific bases for her claim."[115]

In Bass v. Stryker Corp., the United States Court of Appeals for the Fifth Circuit expressed its strong agreement with the Seventh Circuit's decision in Bausch. It noted that "asking the plaintiff to make more specific allegations than those found in Bass's complaint may make pleading a parallel claim regarding defective manufacturing nearly impossible."[116] Similarly, in Wolicki-Gables v.

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[114] See Bausch, 630 F.3d at 558.

[115] See id.; accord Elliot v. Smith & Nephew, Inc., Docket No. 1:12-CV-0070-EJL-MHW, 2013 WL 1622659, at *7-*8 (D. Idaho April 15, 2013) ("Federal Rule of Civil Procedure 9(b) does not impose any special requirement that a products liability claim (even in the context of MDA preemption) be plead with particularity. … Moreover, victims of defective products … may not be able to determine without discovery and further investigation the specific source of the defect (such as whether it was caused by a design or manufacturing defect). … The Court accordingly denies Defendant's Motion to Dismiss.").

[116] See Bass v. Stryker Corp., 669 F.3d 501, 511 (5th Cir. 2012); cf. In re Medtronic, Inc., 623 F.3d 1200, 1209 (8th Cir. 2010) (Melloy, J., dissenting) (observing that Twombly "must be applied in a practical manner that recognizes the parties' relative access to information necessary to articulate claims with specificity"). The majority was largely in agreement with Judge Melloy's views. Indeed, the majority observed in *dicta* that the plaintiffs' argument that the District Court imposed "an impossible pleading standard … would have considerable force in a case where a specific defective Class III device injured a consumer, and the

Arrow International, Inc., the Eleventh Circuit held that a parallel claim has been adequately pled where it "set[s] forth any specific problem, or failure to comply with any FDA regulation that can be linked to the injury alleged."[117]

In this matter, the District Court determined that the allegations in the Second Complaint "are conclusory because they essentially assume that a significant gel bleed occurred based on the results of Plaintiff's pathology report, the nature and extent of her injuries, and the levels of manganese in her system."[118]

This is erroneous. Under Twombly, and otherwise, a "conclusory" allegation would be the bare allegation, unsupported by any facts, that the implants suffered from a manufacturing defect.[119] Here, by contrast, Allergan's own materials demonstrate that the implants suffered from a manufacturing defect. First, Allergan's "Directions for Use" strongly suggests that the implants, when properly manufactured, are safe. The "Directions for Use" states that "[s]mall quantities" of silicone have been found to bleed through an intact implant shell, and this "extremely low level of gel bleed is of no clinical consequence."[120]

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plaintiff did not have access to the specific federal requirements in the PMA prior to commencing the lawsuit." See id. at 1206.

[117] See Wolicki-Gables v. Arrow Int'l, Inc., 634 F.3d 1296, 1301-02 (11th Cir. 2011) (internal quotation marks omitted).

[118] See September 25 Order, Excerpts of Record 001-007.

[119] Cf. Twombly, 556 U.S. at 678 ("the tenet that a court must accept a complaint's allegations as true is inapplicable to threadbare recitals of a cause of action's elements, supported by mere conclusory statements").

[120] See Exhibit A to Second Amended Complaint, Excerpts of Record 094 (underlining added).

Second, Allergan's literature separately states that any data showing that breast implants lead to vision loss or any neurological issue is "insufficient or flawed," suggesting that the breast implants designed by Allergan, when manufactured according to their design, do not cause these issues.[121]

The October 20, 2011, pathology report, and the nature and extent of Ms. Weber's injuries (including vision loss), evidence a significant gel bleed due to improperly manufactured implants. They do not evidence the bleed of "small quantities" of gel or an "extremely low level of gel bleed" of "no clinical consequence" that, according to Allergan, is to be expected by virtue of the product's design. Rather, the symptoms experienced by Ms. Weber – which included vision loss; six weeks of daily migraines; severe lung and breathing difficulties; severe anxiety; tinnitus; severe vertigo; a racing heartbeat; large red strawberries on her arms, and fungal feet; allergic reactions to all medications; and severe chest spasms and tremors[122] – were certainly of "clinical consequence." It is plausible (in fact, it is more than plausible) that the implants Ms. Weber received were different from those approved by the FDA, and deviated from the FDA-approved product specifications and other federal requirements, including the "Quality System Regulations and Current Good Manufacturing Process requirements" that products be manufactured according to their design.

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[121] See Exhibit A to Second Amended Complaint, Excerpts of Record 101.
[122] See Second Amended Complaint, Excerpts of Record 074, ¶ 45.

Moreover, in the FDA Report, the FDA advised that, since Allergan began post-approval studies on June 30, 2009, 900 of the 2,665 devices in the laboratory were defective due to openings in the shell, and of these 900 defective devices, twenty-six suffered from "manufacturing defects," and an additional 336 had defects whose origins Allergan failed to identify. Still more pertinently, the FDA stated that "5.9 percent" of the implants tested by Allergan "had 'Gel Related Observations,' with defects related to gel-related characteristics without loss of shell integrity." As Ms. Weber alleges in her Second Amended Complaint, without discovery, it is unclear what specific type of "defects" the FDA and Allergan were referring to. It would be one thing if the FDA Report stated that there was not a single manufacturing defect; the FDA Report does the opposite.

As Bausch and its progeny make clear, discovery is warranted on any plausibly pled claim of a manufacturing defect. The Complaint is much more than plausible, and never resorts to labels, conclusions, formulas, or bald assertions. At the end of this case, if the jury finds that it is fifty-one percent likely that a manufacturing defect caused Ms. Weber to suffer the damages she alleges, Ms. Weber will be entitled to a verdict.[123] Certainly, the Complaint contains plausible allegations that, if proven, would allow the jury to find it is 100 percent certain, or seventy-five percent likely, or at a minimum fifty-one percent likely that a

[123] See, e.g., Turpin v. Merrell Dow Pharmaceuticals, Inc., 959 F.2d 1349, 1357 (6th Cir. 1992).

manufacturing defect caused Ms. Weber harm. In granting Allergan's Motion to Dismiss, the District Court essentially imposed an absolute certainty requirement at the pleading stage that is more stringent than the more-likely-than-not standard applied at the time of trial. Ms. Weber's claims are built on sound factual and legal grounds, and should not have been dismissed.

CONCLUSION

For the foregoing reasons, the District Court's September 25 Order should be reversed in its entirety, and this matter should be remanded to the District Court for discovery.

Dated: Tuesday, January 14, 2014

Respectfully submitted,

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STATEMENT OF RELATED CASES

The undersigned hereby states, pursuant to Rule 28-2.6, that he is unaware of any related case pending in this Court.

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CERTIFICATE OF COMPLIANCE

I, Alan C. Milstein, hereby certify as follows:

1. This brief complies with the type-volume limitation of Federal Rule of Appellate Procedure 32(a)(7)(B) because this brief contains 8,742 words, excluding the parts of the brief exempted by Federal Rule of Appellate Procedure 32(a)(7)(B)(iii); and

2. This brief complies with the typeface requirements of Federal Rule of Appellate Procedure and the type style requirements of Fed. R. App. P. 32(a)(6) because this brief has been prepared in a proportionally spaced typeface using Microsoft Word for Mac 2011 in Times New Roman, size 14 font.

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CERTIFICATE OF SERVICE

I, Alan C. Milstein, hereby certify that, on the date set forth below, I served a copy of the within opening brief upon the following counsel via this Court's mandatory ECF system:

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I further certify that all participants in the case are registered CM/ECF users and that service will be accomplished by the appellate CM/ECF system.

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